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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/908,884	08/08/97	DONG X	00786/33904

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HM12/0312

EXAMINER

NELSON, A

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 03/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/908,884

Applicant(s)

DONG ET AL.

Examiner

Amy Nelson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-13,15-29,36 and 40-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-13,15-29,36 and 40-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 22.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 1, 2, 4-13, 15-29, 36, and 40-42 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record set forth in the Official action mailed 12/7/98, 7/26/99, 8/8/00. Applicant's arguments and the Dong Declaration filed 2/12/01 have been fully considered but they are not persuasive.

Applicant asserts that Applicant need not provide a description of a representative sample of members of the claimed genus, provided that Applicant teaches structural features which are common to members of the genus. Applicant has clearly described the ankaryin repeat motif present in the claimed genus of nucleic acid molecules. Furthermore, the evidence in the Dong Declaration and the submitted Jin reference strongly support the existence of genes that are structurally and functionally related to the sequence disclosed in Applicant's specification. Specifically, the Jin reference describes an apple *NPR* homolog isolated by hybridization with the Arabidopsis *NPR1* gene (response, p. 5-7).

Examiner responds that, as stated previously, the ankyrin motif is not a structural feature unique to the claimed genus of sequences involved in disease resistance. Moreover, Applicant has

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not described another disease resistance polypeptide comprising an ankaryin repeat, and hence it is not clear that a genus of disease resistance polypeptides comprising an ankaryin repeat even exists. The Jin reference does not provide a description of a nucleic acid molecule, *i.e.* the composition and structure, and the reference is silent as to the presence or absence of an ankaryin motif. Also, the Dong Declaration does not provide a description of a nucleic acid molecule within the claimed genus of nucleic acid molecules.

2. Claims 1, 2, 4-13, 15-29, 36, and 40-42 remain rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for claims limited to an isolated DNA molecule that encodes the polypeptide of SEQ ID NO:14, a vector, transformed host cell, and transgenic plant comprising said DNA molecule, and methods of producing said polypeptide in a host cell, and of providing increased disease resistance in a transgenic plant with said DNA molecule. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is repeated for the reasons of record set forth in the Official actions mailed 12/7/98, 7/26/99, and 8/8/00. Applicant's arguments and the Dong Declaration filed 2/12/01 have been fully considered but they are not persuasive.

Applicant asserts that the instant specification provides guidance for conventional molecular biology methods for isolating structurally related DNAs, and that one of skill in the art could isolate other structurally and functionally related DNAs using the disclosed nucleic acid

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molecule as a probe or using the disclosed oligonucleotide primers (response, p. 3). Examiner responds that Applicant provides only general guidance for isolation of functionally related nucleic acid sequences. Applicant does not provide specific guidance regarding hybridization/ wash conditions or PCR reaction conditions that would allow specific isolation of other structurally and functionally related DNAs.

Applicant also asserts that the cited Jin reference provides evidence of three structurally and functionally related DNAs from apple. Also, the Dong Declaration demonstrates that the instantly disclosed *Arabidopsis* DNA is functional in rice, suggesting the presence of a functionally related DNA in rice (response, p. 4). Examiner responds that the instant claims are directed to structurally related DNAs that encode a polypeptide comprising an ankyrin repeat. There is no teaching in the Jin reference of the presence of an ankyrin repeat motif and hence it is unclear that a structurally and functionally related DNA is disclosed in the Jin reference. Further, although the Dong Declaration suggests the presence of a functionally related DNA in rice, it does not provide definitive evidence demonstrating the existence of a structurally related DNA encoding a polypeptide comprising an ankyrin repeat motif.

3. Claims 10-13, 15-29, 36, and 40-42 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is repeated for the reasons of

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record set forth in the Official action mailed 12/7/98, 7/26/99, and 8/8/00. Applicant's arguments filed 2/12/01 have been fully considered but they are not persuasive.

At Claims 10-12, the phrase "specifically hybridizes to" is indefinite. Applicant asserts that the phrase is defined in the specification to mean "hybridizing to a DNA sequence under at least low stringency conditions as described herein, and preferably under high stringency conditions, also as described herein" which encompasses both low and high stringency conditions. Applicant further asserts that the specification provides exemplary conditions for both low stringency and for high stringency. Hence, one of skill in the art would be reasonably apprised of the scope of the claimed invention (response, p. 13-15). Examiner responds that the scope of the claimed invention would not be clear to one of skill in the art because it is not clear if the claimed invention encompasses nucleic acid molecules which would hybridize at low stringency conditions or those which would hybridize at high stringency conditions, in view of the definition provided in the specification. Also, because the specification provides multiple definitions, and uses of the language "for example" or "may include," Applicant has not provided a clear definition of "low stringency" or of "high stringency." Hence, the metes and bounds of the claimed invention are unclear. Amendment of the claims to simply recite --hybridizes-- or to recite specific hybridization/wash conditions would obviate the instant rejection.

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Claim Rejections - 35 USC § 102

4. Claims 1, 2, 4-13, 15-29, 36, and 40-42 remain rejected under 35 U.S.C. 102(e) as being anticipated by Ryals *et al.* (U.S. Patent 6,091,004; EFD=6/21/96). This rejection is repeated for the reasons of record as set forth in the last Official action mailed 8/8/00. Applicant's arguments filed 2/12/01 have been fully considered but they are not persuasive.

Applicant argues that Ryals does not teach an isolated DNA, as defined by Applicant to mean a "DNA that is free of the genes which, in the naturally-occurring genome of the organism from which the DNA of the invention is derived, flank the gene" (response, p. 10-11). Examiner responds that the instant claims are not directed to an "isolated DNA," but rather to an "isolated nucleic acid molecule," which is not defined in the specification. However, even if Applicant were to amend the claims to recite --isolated DNA--, Examiner submits that further purification of the BAC clone disclosed by Ryals to obtain a gene free of flanking genes as claimed by Applicant would have been obvious in view of Ryals. Ryals discloses, in Provisional Application Serial No. 60/020,272, the isolated DNA clone BAC-04, deposited as ATCC 97543, which comprises the disease resistance NIM gene (p. 61, lines 2-4). The BAC library consists of clones with an average insert size of about 100 kb (p. 49, lines 18-19). The instantly disclosed DNA, which is free of flanking genes, is about 7.5 kb. Hence, it would have been obvious to further isolate the region of the BAC clone which specifically comprises the NIM gene based on the teachings of Ryals.

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Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy J. Nelson whose telephone number is (703) 306-3218. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310. The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application, or if the examiner cannot be reached as indicated above, should be directed to the legal analyst, Yolanda Vines, whose telephone number is (703) 305-2365.

A handwritten signature in black ink, appearing to read "Amy Nelson", with a stylized flourish at the end.

AMY J. NELSON, PH.D
PRIMARY EXAMINER

Amy J. Nelson, Ph.D.

March 9, 2001